REMARKS

In the Office Action, Claims 1-23 and 28-32 were rejected over the prior art as discussed below. In this Amendment, Claims 1, 7, and 18 have been amended. Claims 1-23 and 28-32 remain pending for further consideration.

Personal Interview

Applicant thanks Examiner Bockelman for the courteous and helpful personal interview conducted on June 24, 2008 (summarized above).

Overview of Office Action

In the Office Action, Claims 1-11, 13-23, and 28-32 were rejected as anticipated by or obvious in view of U.S. Patent No. 5,374,245 issued to Mahurkar (Mahurkar); Claims 28, 30-32 were rejected as anticipated by or obvious over U.S. Patent No. 5,766,151 issued to Valley et al. (Valley) either alone or in view of U.S. Patent No. 4,897,077 issued to Cicciu et al. (Cicciu); and Claims 28 and 30 were rejected as anticipated by or obvious in view of Cicciu. Applicant traverses each of these rejections. However, to expedite allowance certain amendments have been made herein. The pending claims are allowable as discussed below.

Rejections Based on Mahurkar

Claims 1-11, 13-23, and 28-32 were rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by or under 35 U.S.C. § 103(a) as being obvious in view of U.S. Patent No. 5,374,245 issued to Mahurkar (Mahurkar). For example, the Examiner refers to a connector portion 354 of the Mahurkar catheter as disclosing an aspect of the subject matter claimed. Although Applicant respectfully disagrees with the rejection, to expedite allowance Applicant has made certain amendments that are consistent with the discussion at the interview summarized above.

Mahurkar Fails to Disclose or Suggest the Claimed Catheter

Mahurkar describes a three lumen catheter for hemodialysis treatment in which a small lumen 318 can be used to deliver medication into a patient's bloodstream or withdraw blood

samples from the patient. Mahurkar at 13:45-50. Figures 45, 48, and 50, reproduced below, illustrate this three-lumen catheter.

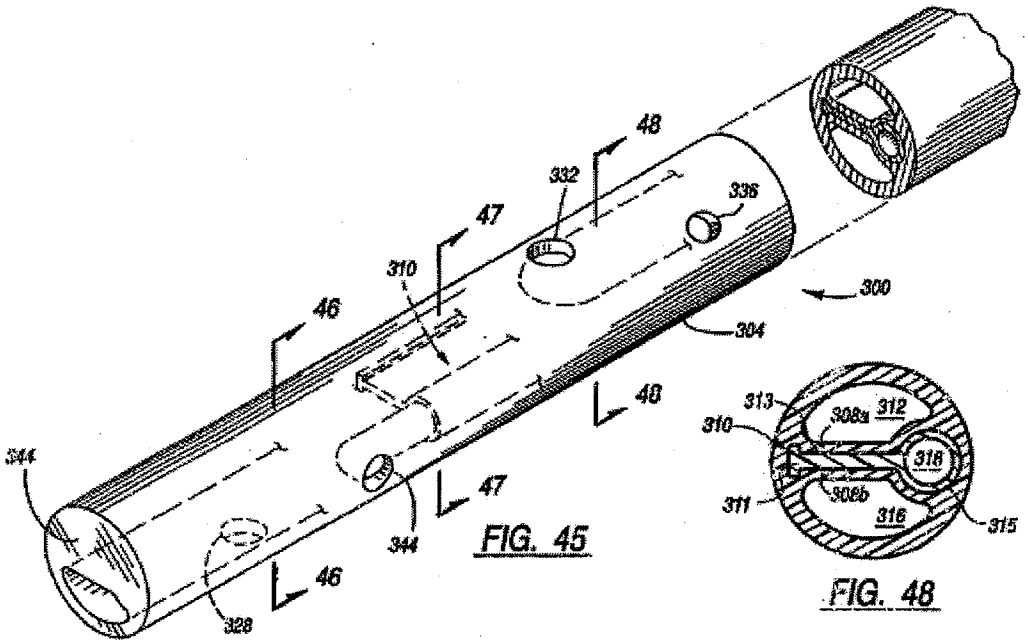

FIG. 45

FIG. 48

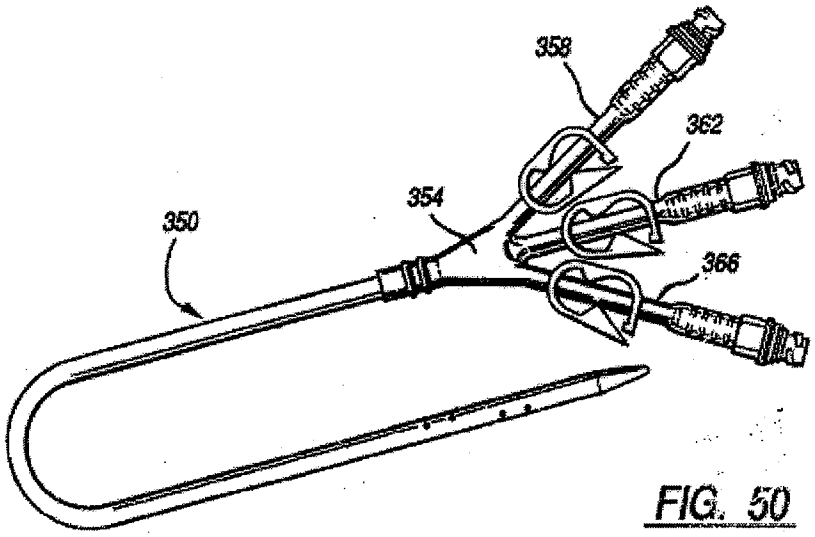

FIG. 50

The Mahurkar catheter as depicted in these figures is directed to a three lumen embodiment where lumen 312 is the blood-intake lumen, lumen 316 is the blood-return lumen, and the lumen 318 is located at one diametral end of the septum between two adjacent corners of the generally D-shaped lumens 312 and 316. Mahurkar at 13:40-45. Additionally, the lumen 318 is normally either filled with heparin anticoagulant solution or closed when it is not being

used for obtaining samples. Mahurkar at 14:42-45. The lumen 318 is fluidly coupled with the hub and also with an extension tube 362 connected to hub 354. The extension tube 362 is similar to those described by Mahurkar as being connectable with a dialysis system, which would be external to the patient's vasculature. *See* at Mahurkar 6:13-31.

Mahurkar does not anticipate or remotely suggest the structure of the present claims. Claim 1 as amended herein recites a multilumen catheter for directing blood through a single cannulation site, said catheter comprising:

> a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally farther from the proximal end than the second distal end, said catheter body configured to enable the catheter to be applied through a single cannulation site;
>
> a first lumen extending between said first distal end and said proximal end;
>
> a second lumen extending between said second distal end and said proximal end; and
>
> a third lumen having a distal end and a proximal end, at least the proximal end of the third lumen positioned distal of the proximal end of the catheter body, such that the distal end and the proximal end of the third lumen are positioned entirely within the patient's vascular system when the multilumen catheter is in use.

Mahurkar lacks, for example, a third lumen having a distal end and a proximal end, at least the proximal end of the third lumen positioned distal of the proximal end of the catheter body, such that the distal end and the proximal end of the third lumen are positioned entirely within the patient's vascular system when the multilumen catheter is in use. In addition, Mahurkar also teaches away from a third lumen that has a proximal end positioned within the vasculature in use because such a lumen could not be used for the purpose Mahurkar's describes in connection with lumen 318, i.e., for withdrawing samples for analysis. For this purpose, the proximal end must be located outside the vasculature in use.

Accordingly, Claim 1 is patently distinct from Mahurkar for at least the reasons noted above. Claims 2-6 and 17 depend from Claim 1 and recite further novel and nonobvious limitations thereon. Therefore, Claims 1-6 and 17 are patentably distinct from Mahurkar for at least the reasons discussed above with respect to Claim 1.

With regards to Claim 7, Claim 7 as amended herein recites a multilumen catheter for directing blood through a single cannulation site, said catheter comprising:

> a catheter body having a proximal end and a distal end, the catheter body having a first lumen for directing blood between a first blood vessel and a device, a second lumen for directing blood between a second blood vessel and said device, and a third lumen having a distal end and a

> proximal end, the third lumen extending along a portion of the catheter body such that the distal end and the proximal end of the third lumen are each positioned between the distal end and the proximal end of the catheter body, wherein the catheter body has a first width at a first location where the first, second, and third lumens are all overlapping and having a second width at a second location that is between the first location and the proximal end, the second width being less than the first width.

Mahurkar does not disclose all of the limitations of amended Claim 7. For example, Mahurkar does not disclose a catheter that has a first width at a first location where first, second, and third lumens are all overlapping and having a second width at a second location that is between the first location and a proximal end, the second width being less than the first width. For these reasons, Claim 7 is distinguishable from Mahurkar. Claims 8-16 depend from Claim 7 and recite additional limitations thereon. Claims 8-16 are therefore allowable for at least the reasons discussed above with respect to Claim 7.

Claim 18 as amended recites an extracardiac pumping system for supplementing blood circulation in a patient without any component thereof being connected to the patient's heart, the extracardiac system comprising:

> a pump configured to pump blood through the patient at subcardiac flow rates; and
>
> a multilumen catheter for directing blood through a single cannulation site, said catheter comprising a first lumen for directing blood between a first blood vessel and said pump, a second lumen for directing blood between a second blood vessel and said pump, and a third lumen having a distal end and a proximal end, the third lumen extending along only a portion of the catheter such that the distal end and the proximal end of the third lumen are each positioned between a distal end and a proximal end of the catheter, the distal end and the proximal end of the third lumen configured to be positioned entirely within the patient's vascular system in use, and wherein the third lumen terminates at the proximal end such that all fluid flowing in the third lumen exits or enters the third lumen through the proximal end.

In contrast, as discussed above, Mahurkar does not disclose and, in fact, teaches away from a lumen that is configured such that all fluid flowing in the lumen exits or enters the lumen through the proximal end thereof, which proximal end is positioned entirely within the patient's vasculature. Such a configuration would prevent samples from being extracted from the patient, as taught by Mahurkar in connection with the lumen 318, which is for withdrawal of samples for analysis. Mahurkar at 14:41-46. Accordingly, Claim 18 is distinguishable from Mahurkar.

Claims 19-23 depend from Claim 18 and recite additional limitations thereon. Claims 19-23 are therefore allowable for at least the reasons discussed above with respect to Claim 18.

Regarding Claim 28, as discussed above, Mahurkar describes a blood-intake lumen 312, a blood-return lumen 316, and a lumen 318 that is "not used to conduct blood except for withdrawal of samples for analysis, and is normally either filled with heparin anticoagulant solution or closed when it is not being used . . . ." Mahurkar at 14:41-45.

Mahurkar does not disclose a multilumen catheter for directing blood through a single cannulation site comprising:

> a catheter body having a proximal end configured to enable the catheter to be applied through a single cannulation site, a first distal end, a second distal end, a first lumen extending between said first distal end and said proximal end, and a second lumen extending between said second distal end and said proximal end;
>
> said first distal end extending farther from the proximal end than the second distal end; and
>
> a means for passively maintaining or enhancing perfusion to the patient's vasculature downstream of a point of entry of said catheter into a blood vessel when said catheter is inserted into the patient for treatment.

For example, no structure in Mahurkar has been identified that is capable of performing the recited function. As discussed above, the lumen 318 is configured for sampling blood and as such must remove the blood from the vessel and form the patient. To accomplish this, the lumen 318 extends outside the patient in use. In fact, the lumen 318 is for a contrary purpose, i.e., sampling or removing blood from the patient, reducing the amount of blood that can flow past the Mahurkar catheter. Accordingly, for at least these reasons, Claim 28 is distinguishable over Mahurkar.

Claim 29 depends from Claim 28 and recites additional limitations thereon. Claim 29 is therefore allowable for at least the reasons discussed above with respect to Claim 28.

Regarding Claim 30, Claim 30 recites a multilumen catheter comprising, among other limitations, "means for passively maintaining or enhancing perfusion to the patient's vasculature downstream of a point of entry of said catheter into a blood vessel when said catheter is inserted into the patient for treatment." As discussed above, Mahurkar does not disclose at least this limitation of Claim 30. Accordingly, Claim 30 is distinguishable over Mahurkar.

Claims 31 and 32 depend from Claim 30 and recite additional limitations thereon. Claims 31-32 are therefore allowable for at least the reasons discussed above with respect to Claim 30.

Rejections Based on Valley & Cicciu

Claims 28 and 30-32 were also rejected in the Office Action under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,766,151 issued to Valley et al. (Valley) either alone or in view of U.S. Patent No. 4,897,077 issued to Cicciu et al. (Cicciu). In addition, Claims 28 and 30 were rejected as being anticipated by or, in the alternative, as being obvious over Cicciu.

For reasons similar to those discussed above in connection with Mahurkar, Claims 28 and 30-32 are distinguishable over Valley and Cicciu. Valley and Cicciu lack specific structure corresponding to the recited means limitations, which structure is provided to maintain or enhance perfusion. The present application discloses exemplary structures for carrying out passive perfusion. For example, the Specification associates the function of passive perfusion with a structure that resides entirely within the patient's body, in certain embodiments. *See, e.g., Specification as Filed* [0026]. A further example of corresponding structure is a third lumen that has a proximal end positionable entirely within the patient's vascular system when the multilumen catheter is in use. Neither Valley nor Cicciu discloses or suggest structures within the recited means limitations of Claims 28 and 30-32. Accordingly, Claims 28 and 30-32 are distinguishable over Valley alone, Cicciu alone, or the combination.

Co-Pending Applications of Assignee

Applicant wishes to draw to the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Docket No.	Title	Filed
10/078,283	FORFLOW.008CP1	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	02/14/02
11/417,509	FORFLOW.008DV3	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/418,499	FORFLOW.008DV4	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/417,652	FORFLOW.8CP1DV1	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/417,662	FORFLOW.8CP1DV2	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/417,918	FORFLOW.8CP1DV3	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06

11/418,377	FORFLOW.8CP1DV4	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/417,647	FORFLOW.8CP1DV5	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/417,937	FORFLOW.8CP1DV6	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/417,487	FORFLOW.8CP1DV7	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
11/418,489	FORFLOW.8CP1DV8	MULTILUMEN CATHETER FOR MINIMIZING LIMB ISCHEMIA	05/03/06
10/735,413	ORQIS.018A	CANNULAE FOR SELECTIVELY ENHANCING BLOOD FLOW	12/12/03

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

CONCLUSION

For the foregoing reasons, it is respectfully submitted that the rejections set forth in the outstanding Office Action are inapplicable to the present claims. Accordingly, issuance of a Notice of Allowance is most earnestly solicited.

Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches. Although amendments have been made, no acquiescence or estoppel is or should be implied thereby. Any arguments in support of patentability and based on a portion of a claim should not be taken as founding patentability solely on the portion in question; rather, it is the combination of features or acts recited in a claim which distinguishes it over the prior art.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney, Andrew M. Douglas at (949) 721-7623 to resolve such issue(s) promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: October 2, 2008

By: 

Andrew M. Douglas
Registration No. 51,212
Attorney of Record
Customer No. 20,995
(949) 760-0404

5722063 // 072908